



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 15 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Roll-Ability (PTY) LTD.  
Mr. Victor F. Myburgh  
President  
c/o Roll-Ability USA  
6162 Steeplechase Drive  
Roanoke, Virginia 24018

Re: K003048  
Trade Name: All Terrain Wheelchair (ATW)  
Regulatory Class: I  
Product Code: IOR  
Dated: September 29, 2000  
Received: September 29, 2000

Dear Mr. Myburgh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

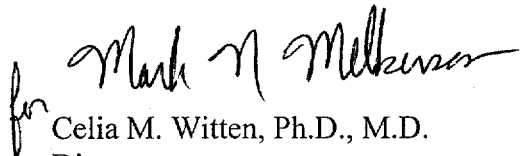
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 – Mr. Victor F. Myburgh

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Mark N. Melanson

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for use page**  
**INDICATIONS FOR USE PAGE**

**Applicant : Victor F. Myburgh**

**510(k) Number ( if known ) : ~~(not yet assigned)~~ K003048**

**Indications for use :**

**The All Terrain Wheelchair** empowers physically challenged persons by providing a means of mobility. This includes ( but not limited to) conditions in all ages such as :

Arthritis

Tetraplegia

Polio

Amputee

Spina Bifida

Multiple Sclerosis

Paraplegia

Muscular Dystrophy

Cerebral Palsy

Hemiplegia

Any other immobilizing or debilitating condition.

**The All Terrain Wheelchair** will be marketed to those seeking a second wheelchair which they can use in rough terrain without fear of damaging their everyday chair. The user may also choose to purchase the optional **hand cycle attachment** which would be used for exercise purposes only. The A.T.W. will not be marketed to first time wheelchair users. It's low price will make it affordable to most interested.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED. )

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Concurrence of CDRH, Office of Device Evaluation (ODE )

PRESCRIPTION USE \_\_\_\_\_ OR OVER-THE-COUNTER-USE \_\_\_\_\_

*Mark N. Miller*  
(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number \_\_\_\_\_

**K003048**